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Jurgen Dannenmaier

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EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

1777

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,546	<b>Applicant(s)</b> DANNENMAIER ET AL.	
	<b>Examiner</b> DIRK BASS	<b>Art Unit</b> 1777	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/9/06, 7/9/10</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 41-42** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 41-42 recite limitations which do not have proper support in their preceding base claims. There is insufficient antecedent basis for the following limitations in the claims.

4. Claim 41 recites "a second pressure measurement chamber" without a previously recited first pressure measurement chamber in parent claim 39. For the purposes of examination, the examiner is interpreting claim 41 to be dependant upon claim 40 instead of claim 39.

5. Claim 42 recites "a third pressure measurement chamber" without a previously recited first or second pressure measurement chamber. For the purposes of examination, the examiner is interpreting claim 42 to be dependant upon claim 41.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 39-61, and 65-86** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevallet et al., US 5441636 (Chevallet) in view of Wamsiedler, US 6176903 (Wamsiedler, IDS).

9. Regarding claim 39, Chevallet discloses an integrated blood treatment module (abstract, fig. 1-2) comprising:

- a. A blood treatment device (REF 40); having:
  - i. A housing (implicit in REF 40) having a longitudinal axis;
  - ii. A first end cap (top of REF 40) closing a first end of the housing, the first end cap having a blood inlet port (REF 42);
  - iii. A second end cap (bottom of REF 40) closing a second end of the housing;
- b. A pump hose (REF 50), wherein the pump hose has a first end that is secured to a supporting member (REF 20) and a second end that is connected to the blood inlet port (REF 53).

10. Chevallet does not explicitly disclose a blood treatment module comprising a degassing device having the features recited in claim 39. However, Wamsiedler

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discloses a device for removing gases from fluids (abstract, fig. 1-2) comprising a first chamber (REF 32) having an inlet for receiving a liquid (REF 38), a second chamber (REF 34) having an opening closed by a hydrophobic membrane (REF 50) and an outlet for discharging a liquid (REF 36), wherein the first chamber has a downstream portion that partially extends within the second chamber and communicates therewith by a passageway (between REF 32 and REF 34), and the second chamber has a downstream portion that extends below the passageway and surrounds the downstream portion of the first chamber.

11. At the time of invention, it would have been obvious to one having ordinary skill in the art to modify the module of Chevallet to include the degassing device of Wamsiedler in order to enable a high separation rate between the dialysis liquids and gases obtained during treatment, and to prevent gases from entering the dialysis circuit during treatment (Wamsiedler, C1/L61-C2/L11).

12. While Wamsiedler does not explicitly disclose a second chamber asymmetrically surrounding the downstream portion of the first chamber it would have been an obvious matter of design choice to asymmetrically surround the downstream portion of the first chamber by the downstream portion of the second chamber since applicant has not disclosed that such a design solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the embodiment disclosed in Wamsiedler.

13. Chevallet (in view of Wamsiedler) discloses a pump hose having a first end secured to a supporting structure but does not explicitly disclose a pump hose having a

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first end secured to the blood treatment device housing. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to locate the pump hose on the housing rather than the support structure, since it has been held that rearranging parts of an invention involves only routine skill in the art where placement of the part would not have modified the operation of the apparatus (MPEP 2144.04, Section VI, Part C).

14. Regarding claim 40, Chevallet (in view of Wamsiedler) discloses a module further comprising a first pressure measurement chamber (REF 55) secured to the blood treatment device and is connected to the first end of the pump hose, the first pressure measurement chamber having a first port.

15. Regarding claim 41, Chevallet (in view of Wamsiedler) discloses a module further comprising a second pressure measurement chamber (REF 75) that is secured to the blood treatment device and is connected to the outlet port of the degassing device, the second pressure measurement chamber having a second port.

16. Regarding claim 42, Chevallet (in view of Wamsiedler) discloses a module further comprising a third pressure measurement chamber (REF 56) secured to the blood treatment device and is connected to the second end of the pump hose, the third pressure measurement chamber having a third port.

17. Regarding claims 43 and 77, Chevallet (in view of Wamsiedler) discloses a module further comprising a support structure (REF 20) having a plurality of conduits defined therein, the blood treatment device being secured to the support structure.

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18. Regarding claim 44, Chevallet (in view of Wamsiedler) discloses a module wherein the support structure comprises a first conduit having a first end connected to a first access port of the housing (REF 48), and a second end comprised of an outlet nozzle (REF 103) for a waste liquid.

19. Regarding claim 45, Chevallet (in view of Wamsiedler) discloses a module wherein the support structure comprises a second conduit having a first end connected to a second access port of the housing (REF 46), and a second end comprised of an inlet nozzle (REF 92) for a dialysis liquid.

20. Regarding claims 46 and 78, Chevallet (in view of Wamsiedler) discloses a module wherein the support structure further comprises a third conduit having an inlet for connection to a blood withdrawal tube (REF 52) and an outlet connected to the first end of the pump hose (REF 54), and a fourth conduit having an inlet connected to the second end of the pump hose and an outlet (REF 53) connected to the blood inlet port of the first end cap.

21. Regarding claim 47, Chevallet (in view of Wamsiedler) discloses a module wherein the support structure comprises a fifth conduit (REF 83) having a first end connected to the fourth conduit and a second end for connection to a predilution infusion tube.

22. Regarding claim 48, Chevallet (in view of Wamsiedler) discloses a module further comprising a first pressure measurement chamber (REF 55) defined within the support structure and connected to the third conduit.

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23. Regarding claims 49 and 79, Chevallet (in view of Wamsiedler) discloses a module wherein the outlet of the third conduit (REF 42) and the inlet of the fourth conduit (REF are arranged with respect to each other so that the pump hose forms a loop that extends in a plane substantially parallel to the longitudinal axis of the housing (fig. 1-2).

24. Regarding claim 50, Chevallet (in view of Wamsiedler) discloses a module wherein the outlet of the third conduit is located between the two end caps and the loop formed by the pump hose extends laterally with respect to the housing fo the blood treatment device (fig. 1-2).

25. Regarding claim 51, Chevallet (in view of Wamsiedler) discloses a module wherein the outlet of the third conduit is located along the longitudinal axis of the housing beyond the first end cap, and the loop formed by the pump hose is offset along the longitudinal axis of the housing with respect to the housing of the blood treatment device (fig. 1-2).

26. Regarding claims 52 and 80, Chevallet (in view of Wamsiedler) discloses a module wherein the outlet of the third conduit and the inlet of the fourth conduit are arranged with respect to each other so that the pump hose forms a loop that extends in a plane inclined with respect to a plane substantially perpendicular to the longitudinal axis of the housing (fig. 1-2).

27. Regarding claim 53, Chevallet (in view of Wamsiedler) discloses a module wherein the support structure comprises a conduit having an inlet (REF 71) connected



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to the outlet port of the blood degassing device and an outlet (REF 73) for connection to a blood return tube.

28. Regarding claim 54, Chevallet (in view of Wamsiedler) does not explicitly disclose a support structure comprising a conduit having a first end connected to the blood return tube and a second end for connection to a post dilution infusion tube. However, Chevallet (in view of Wamsiedler) discloses a module wherein the conduit for returning blood (REF 70) comprises a blood sampling port (REF 74). It can be envisaged that the blood sampling port can function as a port for post dilution infusion in conjunction with a conduit since Chevallet (in view of Wamsiedler) discloses a pre-dilution conduit (REF 60 connected to the blood inlet (REF 50) and replicating such a conduit would have been obvious to a routineer in the art.

29. Regarding claim 55, Chevallet (in view of Wamsiedler) discloses a module further comprising a pressure measurement chamber (REF 75) within the support structure and connected to the conduit.

30. Regarding claim 56, Chevallet (in view of Wamsiedler) discloses a module further comprising a pressure measurement chamber (REF 56) connected to the conduit for measuring a pressure upstream of the pump hose, wherein the measurement chamber has a port (implicit in REF 56), and wherein the inlet nozzle, outlet nozzle, and ports of the pressure measurement chambers have respective central axes that are substantially parallel (fig. 1-2).

31. Regarding claim 57, Chevallet (in view of Wamsiedler) discloses a module wherein the respective central axes of the inlet nozzle, outlet nozzle, and ports of the

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pressure measurement chambers are substantially perpendicular to the longitudinal axis of the housing (fig. 1-2).

32. Regarding claims 58 and 81, Chevallet (in view of Wamsiedler) do not explicitly disclose that the downstream portion of the second chamber has a bottom wall that is inclined with respect to the longitudinal axis of the degassing device. However, it would have been an obvious matter of design choice to shape the bottom wall of the second chamber in such a way since applicant has not discloses that doing so solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the embodiment described above.

33. Regarding claim 59, Wamsiedler further discloses that the downstream portion of the first chamber (REF 32) has a lateral wall that is concentric to the lateral wall of the second chamber (REF 34, fig. 1-2).

34. Regarding claim 60, Wamsiedler further discloses that the lateral wall of the downstream portion of the first chamber and the lateral wall of the downstream portion of the second chamber are substantially cylindrical (fig. 1-2).

35. Regarding claim 61, Wamsiedler further discloses the downstream portion of the first chamber has a cross section that is substantially the same as a cross section of the passageway between the first and the second chambers (REF 32/34, fig. 1).

36. Regarding claim 65, Wamsiedler further discloses that the outlet port (REF 36) opens in the downstream portion of the second chamber at a location furthest to the passageway (fig. 1).

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37. Regarding claims 66-69 and 83-84, the limitations with respect to selecting a cross-section so that a specific flow rate or ratio is satisfied are deemed to be statements with regard to the intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. MPEP § 2111.02.

38. Regarding claim 70, Wamsiedler further discloses the downstream portion of the second chamber forms an overflow for a fluid flowing from the first chamber into the second chamber (fig. 1).

39. Regarding claims 71-73 and 85-86, Wamsiedler further discloses that the first chamber, second chamber, and passageway therebetween are arranged with respect to each other so that a flow pattern of a liquid flowing from the first chamber through the second chamber and to the outlet comprises a component that is tangential to the membrane.

40. Regarding claim 74, Wamsiedler further discloses a protective member (REF 18) for protecting the hydrophobic membrane.

41. Regarding claim 75, Wamsiedler further discloses the hydrophobic membrane arranged in a plane that is substantially perpendicular to a longitudinal axis of the degassing device (fig. 1).

42. Regarding claim 76, Chevallet (in view of Wamsiedler) discloses that the blood treatment device is a hemodialyzer, a hemofilter, or a plasmafilter (abstract).

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43. **Claims 39, 43-45, 61-73, 75-78, and 82-86** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipps et al., US 4231871 (Lipps, IDS) in view of Conti, EP 0292445 (Conti, IDS).

44. Regarding claim 39, Lipps discloses a blood treatment module (abstract, fig. 10), said module comprising:

- c. A blood treatment device (REF 177), said device comprising:
  - iv. A housing having a longitudinal axis;
  - v. A first end cap (bottom of REF 126) closing a first end of the housing, the first end cap having a blood inlet port (REF 145); and
  - vi. A second end cap (top of REF 126) closing a second end of the housing;
- d. A pump hose (REF 181) having a first end secured to the housing and a second end that is connected to the blood inlet port; and
- e. A degassing device connected to the second end cap, said degassing device comprising:
  - vii. A first chamber (REF 124) having an inlet for receiving a liquid flowing into the second end cap; and
  - viii. A second chamber (REF 158) having an opening (REF 156) closed by a hydrophobic membrane (REF 157) and an outlet for discharging the liquid (bottom of REF 158), wherein the first chamber has a downstream portion that partially extends within the second chamber and

communicates therewith by a passageway (between REF 124 and REF 158).

45. Lipps discloses that the second chamber has a downstream portion that extends below the passageway (see fig. 10) but does not explicitly disclose that the downstream portion asymmetrically surrounds said downstream portion of the first chamber.

However, Conti discloses an integrated degassing device having a first chamber (REF 12), a second chamber (REF 13), and an outlet (REF 10) for discharging liquid wherein the first chamber has a downstream portion that partially extends within the second chamber and communicates therewith by a passageway (REF 14), and the second chamber has a downstream portion that extends below the passageway and asymmetrically surrounds the downstream portion of the first chamber.

46. At the time of invention, it would have been obvious to one having ordinary skill in the art to modify the module of Lipps to include the particulars of the degassing device disclosed in Conti since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

47. Furthermore, it would have been an obvious matter of design choice to asymmetrically surround the downstream portion of the first chamber by the downstream portion of the second chamber since applicant has not disclosed that such a design solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the embodiment disclosed in Lipps.

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48. Regarding claims 43 and 77, Lipps (in view of Conti) discloses a module further comprising a support structure having a plurality of conduits defined therein, the blood treatment module being secured to the support structure (fig. 12).

49. Regarding claim 44, Lipps (in view of Conti) discloses a module wherein the support structure comprises a first conduit (implicit in fig. 12) having a first end connected to a first access port of the housing (REF 142, fig. 10) and a second end comprised of an outlet nozzle for a waste liquid (implicit in fig. 12).

50. Regarding claim 45, Lipps (in view of Conti) discloses a module wherein the support structure comprises a second conduit (implicitly disclosed in fig. 12) having a first end connected to a second access port of the housing (REF 132, fig. 10) and a second end comprised of an inlet nozzle for dialysis liquid (implicit in fig. 12).

51. Regarding claim 61, Lipps (in view of Conti) discloses a module wherein the downstream portion of the first chamber has a cross-section that is substantially the same as a cross section of the passageway between the first and the second chambers (fig. 10).

52. Regarding claim 62, Lipps (in view of Conti) discloses a module wherein the first chamber comprises an upstream portion having a decreasing cross-section (REF 124, fig. 10).

53. Regarding claims 63-64 and 82, Lipps (in view of Conti) discloses a module wherein the second chamber comprises an upstream portion extending above the passageway that has a frusto-conical shape with a larger cross section that is

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substantially level with the passageway and a smaller cross section that is substantially level with the hydrophobic membrane (REF 158, fig. 10).

54. Regarding claim 65, Lipps (in view of Conti) discloses a module wherein the outlet port opens in the downstream portion of the second chamber at a location furthest to the passageway (fig. 10).

55. Regarding claims 66-69 and 83-84, the limitations with respect to selecting a cross-section so that a specific flow rate or ratio is satisfied are deemed to be statements with regard to the intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. MPEP § 2111.02.

56. Regarding claim 70, Lipps (in view of Conti) discloses a module wherein the downstream portion of the second chamber forms an overflow for a fluid flowing from the first chamber into the second chamber (fig. 10).

57. Regarding claims 71-72 and 85, Lipps (in view of Conti) discloses a module wherein the first chamber, second chamber, and passageway therebetween are arranged with respect to each other so that a flow pattern of a liquid flowing from the first chamber through the second chamber and to the outlet port comprises a component that is tangential to the membrane (fig. 10).

58. Regarding claims 73 and 86, Lipps (in view of Conti) discloses a module wherein the first chamber, second chamber, and passageway therebetween are arranged with

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respect to each other so that a flow of liquid flowing from the first chamber through the second chamber and to the outlet keeps gas bubbles in motion along an inner surface of the hydrophobic membrane (fig. 10).

59. Regarding claim 75, Lipps (in view of Conti) discloses a module wherein the hydrophobic membrane is arranged in a plane substantially perpendicular to a longitudinal axis of the degassing device (fig. 10).

60. Regarding claim 76, Lipps (in view of Conti) discloses a module wherein the blood treatment device is a hemodialyzer, hemofilter, or plasmafilter (abstract).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571)270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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